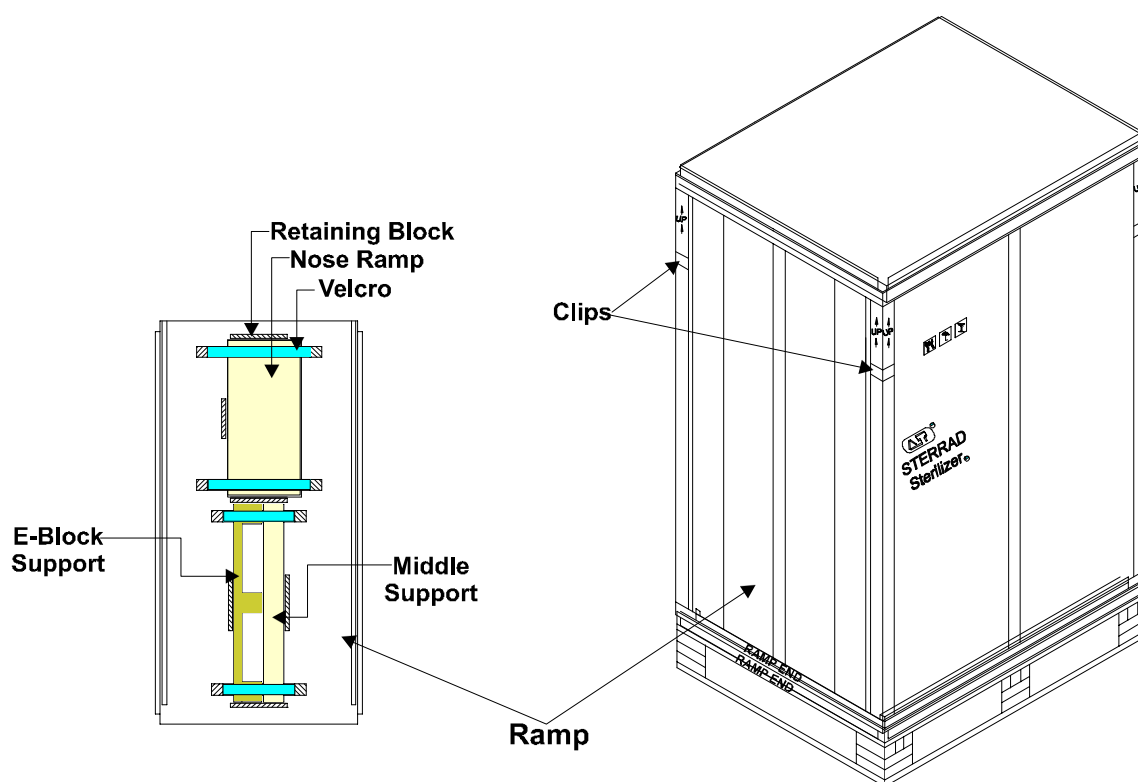


# STERRAD<sup>®</sup> 100S Sterilizer Installation Guide

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ADVANCED STERILIZATION PRODUCTS<sup>®</sup>

a *Johnson & Johnson* company

Division of Ethicon, Inc.

# STERRAD<sup>®</sup> 100S Sterilizer

## Installation Guide

Manufacturer:



ADVANCED STERILIZATION PRODUCTS<sup>®</sup>

a *Johnson & Johnson* company

Division of Ethicon, Inc.

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# **Chapter 1.**

# **Installation**

# **Overview**

# Introduction

This section describes how to uncrate, assemble, set up and initialize a new STERRAD® 100S Sterilization System. Following initialization, the system performance must be verified using the product certification procedures. This installation procedure is for the Block 2 systems as 1.8 systems are no longer available for new installation. If you have an unusual circumstance where you are installing a system version that is not a STERRAD 100S Block 2.0 System, please contact ASP Technical Support for further information.

## Installation Forms

A number of forms are required by ASP Customer Support to complete the installation process. ASP Field Service Engineers can obtain these forms from the ASP Knowledge Center or by contacting ASP Customer Support. Full-sized installation drawings are available on request by contacting ASP Customer Support. As of this publication, these are the current forms; please be sure you have the latest revision of each form prior to proceeding with your installation.

Name	Form Number
Functional Test Record Sheet 1010X	15-01578-001 rev C
STERRAD 100S Sterilizer Check List	15-09743-001 rev B
Installation Validation Report	LC-2023X-003 rev B
Installation Requirement (drawing)	09-00909-1-XXX rev F

***IMPORTANT! The STERRAD® 100S Sterilization System must only be installed by ASP-trained technicians. Installation by any other group or persons without the permission of ADVANCED STERILIZATION PRODUCTS, a Johnson & Johnson company, may void the sterilizer warranty.***

# Physical Specifications

System Dimensions	
Dimensions	765 mm W x 1660 mm H x 1020 mm D (30 <sup>2</sup> W x 65.5 <sup>2</sup> H x 40 <sup>2</sup> D)
Appearance	FED color specification #26408 Block 2 has a custom color
Weight	Approximately 325 Kg (700 lbs)
Shipping Weight	Approximately 350 Kg (750 lbs)
Chamber	
Volume	173 liter (6.1 cubic feet)
Usable Volume	100 liter (3.5 cubic feet)
Inside Length	810 mm (32 inches)
Inside Diameter	510 mm (20 inches)
Shelving	
Upper Shelf Dimension	700 x 425 mm (28 <sup>2</sup> x 17 <sup>2</sup> ) 700 x 426 mm ( 28 <sup>2</sup> x 16.7 <sup>2</sup> ) Block 2
Lower Shelf Dimension	760 x 425 mm (30 <sup>2</sup> x 17 <sup>2</sup> ) 760 x 325 mm (30 <sup>2</sup> x 12.8 <sup>2</sup> ) Block 2
Shelving Strength	25 kgs (55 lbs) uniformly distributed per shelf
Shelving Materials	Passivated stainless steel and polyethylene
Top Shelf Adjustment	Removable. Shelf slides out of chamber to one half of its length.
Bottom Shelf Adjustment	Fixed

# Environmental Conditions

Transport and Storage	
Ambient Temperature	-40 to +70° C (50 to 104° F)
Relative Humidity	10 to 100% including condensation
Atmospheric Pressure	500 hPa to 1060 hPa
Operation	
Ambient Temperature	+10 to 40° C (50 to 104° F)
Altitude	-100 to 3000 m above msl (-330 to 10,000 ft above msl)
Relative Humidity	0 to 95% RH, non-condensing
Atmospheric Pressure	700 hPa to 1060 hPa
Surface	The floor at the installation is flat and level to + 5 mm/M.
Installation Space Requirements	In operation, the system shall not be placed closer than 50 mm (2 in) to a wall at the rear and/or sides of the system. The system should be installed in a space of sufficient size to permit access to all four sides of the system when the system is rolled away from the rear and/or side walls a distance of 3 meters (10 ft), the extent of the power cord. Service access should allow for a minimum clearance of one meter (3 ft) on all sides of the system.
Mobility	The sterilizer is designed to be free standing and self contained with no required connections other than the electrical power cord. The sterilizer is equipped with wheels that allow it to be rolled easily from one location to another. The unit is also equipped with adjustable feet at the front of the unit if leveling is required.



# Electrical Requirements

Voltage Specification	
<b>IMPORTANT WARNING!</b>	Prior to relocating the sterilizer to a new power source, electrical phase rotation should be checked by a qualified technician. Failure to verify phase rotation may cause damage to the system and void the warranty.
208V 60 Hz Power 200V and 208V (Block 2)	For versions employing 208V, 60 Hz power, the sterilizer requires a NEMA L21-20 five wire grounding twist lock outlet attached to a dedicated 20 Amp 3 phase 208 Volt circuit with separate neutral and ground conductors.
380 - 415V 50 Hz Power 380V, 398V and 415V (Block 2)	The sterilizer requires a five wire grounding outlet attached to a dedicated 10 AMP, 3 phase, 380V circuit with separate neutral and ground conductors.
Phase Rotation	The system requires CBA phase rotation. The phase rotation is adjusted to match the system requirements at installation.
Power Calculation	Phase A 228 W-hours per cycle Phase B 158 W-hours per cycle Phase C 177 W-hours per cycle Total 563 W-hours per cycle
Heat Generation	1919 Btu per cycle

## Heater Impedance

Heater Location	Impedance
Door	190 Ohms
Chamber	100 Ohms

# Thermocouples

Thermocouples	Measurement	Location
TC1	42°-50° C	Top of chamber behind injector valve
TC2	42°-50° C	Bottom of chamber near door
TC3	42°-50° C	Middle of door
TC4	42°-50° C	Edge of door

# Standards

Agency	Description
EPA/OSHA	Maximum hydrogen peroxide ambient concentration: less than 1 PPM (8 hour weighted average). Tested average was 0.014 PPM.
NEC	The system meets all applicable National Electrical Code (US) standards.
VDE	VDE 871 certification. Report Number 91287V.
FCC	The system meets all FCC Class A, IEC CISPR requirements.
CSA	All electrical components are CSA approved. Block 2 meets CSA requirement certificate number LR-103178-1
IEC	IEC 601-1 Medical Equipment Safety Certification. File Number 112 MT 14880.
LA	City of Los Angeles Electrical Testing Lab Approval. Application Number 330300
TUV	Meets TUV requirements.
NSTA	The shipping container includes an integral pallet which meets US and International standards. The package provides protection for the machine to pass NSTA tests ASTM D-999 and FED-STD-101.
NRTL/C	Block 2 meets UL standard 1262-Laboratory Equipment

# System Configuration

STERRAD® 100S Sterilization systems are generic until the configuration kit is installed. Configuration kits contain language specific software, membrane panel, a power label, and a language-specific user's guide. It also contains voltage specific parts; thermal overload relay and one of the Configuration PWAs

## STERRAD® 100S Sterilizer Configuration Kit – USA

Domestic product configurations require that you order sterilizer part number 10101 and the following configuration kit.

Country	Language	Voltage	Configuration Kit
USA	English	208V	05-09786-X-001

## STERRAD® 100S Sterilizer Configuration Kit - International

International product configurations require that you order sterilizer part number 00-10101-X-001 and the specific configuration kit from the following table:

Country	Language	Voltage	Configuration Kit
Argentina	Spanish	380V	05-06421-X-003
Australia	English	415V	05-06420-X-005
Austria	German	380V	05-06424-X-003
Benelux	English	380V	05-06428-X-003
Benelux	French	380V	05-06423-X-003
Benelux	German	380V	05-06424-X-003
Brazil	English	208V	05-06427-X-002
Canada	English	208V	05-06420-X-002
Canada	French	208V	05-06423-X-002
Chile	Spanish	380V	05-06421-X-003
Colombia	Spanish	208V	05-06421-X-002
Czech Republic	English	380V	05-06420-X-003

<b>Country</b>	<b>Language</b>	<b>Voltage</b>	<b>Configuration Kit</b>
Ecuador	Spanish	208V	05-06421-X-002
Finland	Finnish	380V	05-06426-X-003
France	French	380V	05-06423-X-003
Germany	German	380V	05-06424-X-003
Greece	Greek	380V	05-51269-X-003
Hong Kong	English	380V	05-06420-X-003
Hungary	English	398V	05-06430-X-004
Indonesia	English	415V	05-06420-X-005
Ireland	English	380V	05-06420-X-003
Italy	Italian	380V	05-06422-X-003
Japan	English	200V	05-06429-X-001
Korea	English	380V	05-06420-X-003
Malaysia	English	415V	05-06420-X-005
Mexico	Spanish	208V	05-06421-X-002
Middle East	English	208V	05-06420-X-002
Middle East	English	415V	05-06420-X-005
Panama	Spanish	208V	05-06421-X-002
Peru	Spanish	208V	05-06421-X-002
Philippines	English	208V	05-06420-X-002
Poland	English	380V	05-06420-X-003
Portugal	English	380V	05-06427-X-003
Puerto Rico	English	208V	05-06420-X-002
Puerto Rico	Spanish	208V	05-06421-X-002
Singapore	English	415V	05-06420-X-005
South Africa	English	380V	05-06420-X-003
Spain	Spanish	380V	05-06421-X-003
Sweden	Swedish	380V	05-06425-X-003
Switzerland	French	380V	05-06423-X-003
Switzerland	German	380V	05-06424-X-003
Switzerland	Italian	380V	05-06422-X-003
Taiwan	English	208V	05-06420-X-002

Country	Language	Voltage	Configuration Kit
Thailand	English	380V	05-06420-X-003
United Kingdom	English	415V	05-06420-X-005
Uruguay	Spanish	380V	05-06421-X-003
Venezuela	Spanish	208V	05-06421-X-002
Generic (200V)	English	200V	05-06420-X-001
Generic (208V)	English	208V	05-06420-X-002
Generic (380V)	English	380V	05-06420-X-003
Generic (398V)	English	398V	05-06420-X-004
Generic (415V)	English	415V	05-06420-X-005

## Tools and Test Equipment

The following items may be needed to perform the service procedures for the STERRAD 100 Sterilizer. Included are parts needed for chamber heater and feedthrough replacement.

Manufacturer	Model or ASP Part Number	Where Used
Metric Tool kit	Local Supplier	All maintenance
Digital multimeter (DMM) accurate to 3 decimal places	Fluke 87 or equivalent	Certification and calibration
Temp. Probe -50°C to +150°C	Fluke 80T-150U	Certification and calibration
Service Access Key	04-09071-0-001	Repairs, certification and calibration
LFPS Power Tester	35-50384-0-001	Certification
Adjustment Tool Baratron	35-02211-001	Certification and calibration
Vaporizer spanner wrench	35-03000-001	Repairs
Omega Thermometer with J-type thermocouple cable	Omega HH-81 or equivalent.	Certification and calibration
Cassette Alignment Tool	35-50494-1-001	Injector pump calibration.
Baratron Zero Shift Test Kit (Vacuum Gauge Kit)	35-04264-001	Capacitance manometer testing



# **Chapter 2.**

# **For Your Safety**

## Overview

Your safety is of primary concern to ASP. This section provides information on safely using the sterilizer. You must read, understand, and use the information in this section before operating the unit. Also, always pay attention to the warnings, cautions, and notes throughout this guide. This information is for your safety and to ensure that you receive the most benefit from the safe installation, operation, and maintenance of the STERRAD 100S Sterilization System. Only trained, experienced technicians, who are fully acquainted with the unit, should install, repair, or adjust the STERRAD System.

## Personal Safety and First Aid

- Installation procedure should be performed with the SYSTEM TURNED OFF AND THE POWER CORD DISCONNECTED until you are ready to verify system function.
- IT IS REQUIREMENT OF ASP TECHNICAL SERVICES, INC. THAT ALL ASP FIELD SERVICE ENGINEERS WEAR SAFETY GOGGLES WHEN SERVICING ASP PRODUCTS.
- For canceled cycles WEAR LATEX OR VINYL GLOVES WHILE REMOVING ITEMS FROM THE STERILIZER. CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT. If a cycle cancels and the items in the load have any visible moisture or liquid, hydrogen peroxide may be present.
- Direct hydrogen peroxide contact with the skin can cause severe irritation. If skin contact occurs, immediately flush with large amounts of water. If symptoms are severe or persist, consult a physician immediately.
- Direct hydrogen peroxide contact with eyes can cause irreversible tissue damage. If eye contact occurs, immediately flush with large amounts of water and immediately consult a physician.
- Inhalation of mist can cause severe irritation of lungs, throat, and nose. If inhalation occurs, move to fresh air and consult a physician immediately.



- Ingestion can produce injury that may be life threatening. If swallowed, drink plenty of water immediately to dilute. Do not induce vomiting. Consult a physician.
- If hydrogen peroxide comes into contact with organic material (such as greasy surfaces) it can be a fire hazard.

## **Safe Maintenance**

- Repairs and adjustments should only be attempted by experienced technicians who are fully trained to maintain and repair the STERRAD 100S Sterilizers.
- Use of unauthorized parts for maintenance or repair could cause personal injury, result in costly damage or unit malfunction, and void the warranty.
- Do not clean the chamber door area with abrasives. The sterilization chamber uses an O-ring vacuum seal to maintain a vacuum in the chamber. Never use rough cleaning tools, such as a wire brush or steel wool, on the door housing or chamber assembly. This could damage the seal.
- Do not change the power source without checking the electrical phase rotation. Prior to relocating the sterilizer to a new power source, electrical phase rotation should be checked. Failure to verify and match phase rotation may cause damage to the sterilizer.

## Cassette Handling

- STERRAD CASSETTES CONTAIN CONCENTRATED HYDROGEN PEROXIDE, A STRONG OXIDIZER. CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT. Direct contact with the skin can cause severe irritation. If skin contact occurs, immediately flush with large amounts of water. If symptoms are severe or persist, consult a physician immediately. Direct contact with eyes can cause irreversible tissue damage. If eye contact occurs, immediately flush with large amounts of water and immediately consult a physician. Inhalation of mist can cause severe irritation of lungs, throat, and nose. If inhalation occurs, move to fresh air and consult a physician immediately. Ingestion can produce corrosion that may be life threatening. If swallowed, drink plenty of water immediately to dilute. Do not induce vomiting. Consult a physician.
- Do not remove the plastic wrapper from the cassette package if the indicator strip is red. Red indicates that the cassette might have been damaged.
- Do not remove used cassettes from the protective cardboard sleeve. Dispose of the cassette inside the protective sleeve in normal waste or follow the facility's procedures. Empty or expired cassettes must be replaced prior to starting the cycle.
- If it is necessary to handle a used cassette that is not in the cardboard sleeve, wear latex or vinyl gloves. Do not touch your gloved hands to your face or eyes.
- FOR ROUTINE HANDLING, MINIMUM PPE REQUIREMENTS INCLUDE APPROVED; (e.g., ANSI Z87.1), CHEMICAL SPLASH GOGGLES, NITRILE OR LATEX GLOVES, AND A CHEMICAL RESISTANT; (e.g., polyolefin fiber), LAB COAT. WHERE THERE IS A RISK OF PRODUCT CONTACT WITH SHOES, CHEMICAL RESISTANT SHOE COVERINGS ARE RECOMMENDED. WHERE THERE IS RISK OF PRODUCT SPLASHING INTO EYES, AN INDEPENDENT FACE SHIELD MUST BE WORN IN ADDITION TO CHEMICAL SPLASH GOGGLES as authorized in 29 CFR 1910.133, applicable U.S. State regulations, or the appropriate standards of Canada and its Provinces or EC Member States (per European Standard EN 166).

## Device Safety

- The chapter on Preparing Items To Be Sterilized in the STERRAD 100S User's Guide contains information about materials and devices that can be processed by the sterilizer. Make sure your customer is familiar with that section prior to using the sterilizer.
- Metal objects must not come into contact with the chamber walls, the door, or the electrode. Contact with the walls, door, or electrode could damage the sterilizer or the instruments.
- Warn the customer that they must not change the power source without checking the electrical phase rotation. Also, prior to relocating the sterilizer to a new power source, electrical phase rotation should be checked. Failure to verify and match phase rotation may cause damage to the sterilizer.



# **Chapter 3.**

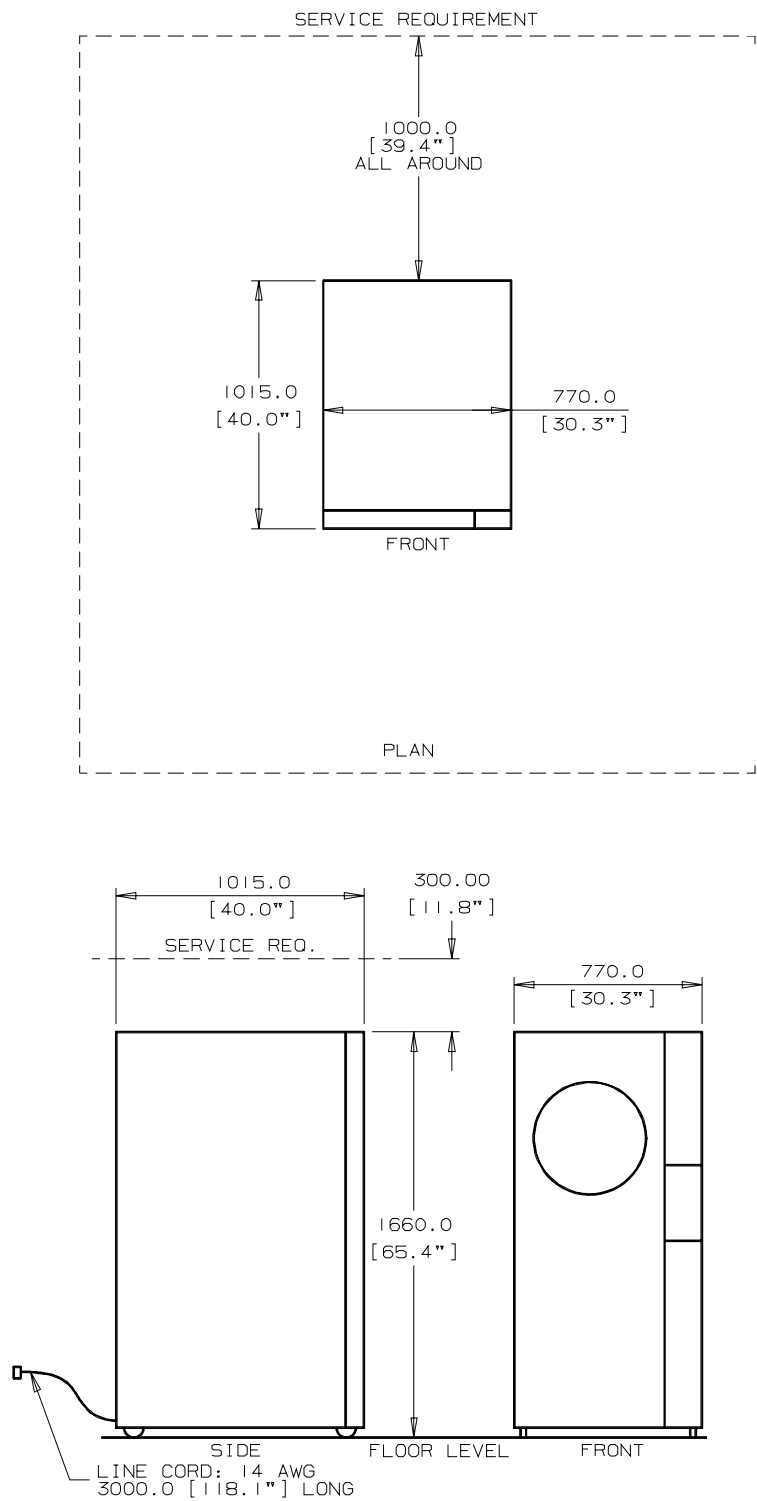
# **Installation**

## Pre-Installation

Perform the following steps prior to uncrating the system. It is a good idea to have performed these steps prior to delivery of the system.

*Note: If the seismic restraint is being installed, the hospital must have identified the location of the restraints and have pre-drilled the proper holes.*

1. Prior to your arrival, verify the number of cartons and items shipped to the customer.
2. Confirm that a proper location exists for correct installation; the location should be the correct size for the unit with the needed amount of clearance in front and on the cassette access side if necessary.



Service Requirement

Figure 1. Installation Diagram

3. Verify that the AC power connection is in place, is the proper voltage and phase rotation, and is activated. If the power requirements are not met, notify the hospital engineering department immediately so they can correct the problem. The phase rotation should be CBA, that is, it should be counterclockwise from standard ABC phase rotation.
4. Make sure that the "route" from the delivery area to the installation area is large enough to accommodate the system and is not blocked by other equipment.
5. At the customer site, verify that the system and all necessary operating supplies have arrived.

## Uncrating the System

The Accessory Installation Kit consists of two boxes. One is on top of the unit; the other is inside the cassette chute. The side of the crate that forms the ramp is marked at the bottom of the crate. Be sure the ramp and ramp supports are securely positioned before moving the system.

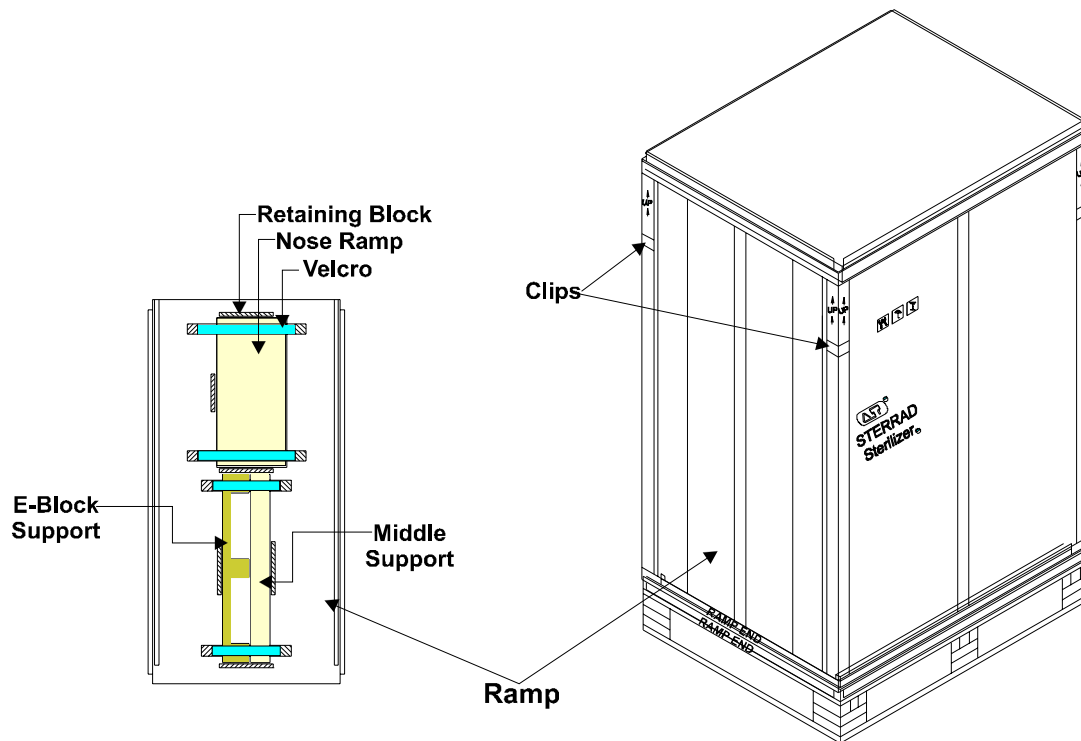


Figure 2. Uncrating the System.



1. Position the crate on a level surface so that the ramp side faces an open area large enough for the ramp to be extended and the unit removed.
2. Cut the banding and immediately dispose of it.
3. Using a screwdriver remove the two clips holding the ramp in place.

*Note: The crate panels fit together with a tongue and groove mechanism. The top must be lifted off the sides and the sides must be lifted up from the pallet base.*

4. Slightly lift the top, then lift-up and lower the ramp.
5. Holding the Velcro straps, position the end of the ramp onto the crate and fasten the Velcro tabs. Unfasten the support blocks from the ramp.
6. Slide the nose ramp under the end of the main ramp.

*Note: The middle support and the E-block support are angled to fit the angle of the ramp.*

7. Position the middle support under the center of the ramp and place the E-block support at the top of the ramp near the crate.
8. Remove the remaining clips, the top, and the other three sides. Remove the foam protectors.
9. Remove the box on top of the unit.
10. Remove the system panels and, using a 14 mm (9/16") deep socket wrench, remove the hold-down bolts securing the machine to the pallet. To remove the front bolt, slide the cassette storage drawer forward in order to reach the bolt. Remove the water drain bottle to reach the rear bolt. Remove the 4 x 4 block held in by the rear bolt.
11. Verify that the levelers in the front of the system are in the fully retracted (up) position.
12. Drape the electrical cord next to the vacuum pump to keep it out of the way.

**WARNING! USE A PARTNER. FOR SAFETY PURPOSES, THIS STEP REQUIRES THE PRESENCE OF AT LEAST TWO PEOPLE CAPABLE OF HANDLING 100 LBS.**

13. With one person pushing carefully at the back of the system and one person guiding the system at the front, ease the system forward and guide it down the ramp until all four wheels are on the floor.
14. Verify that no air pressure is present in the pneumatics.
15. Remove the blanking flange from the bottom of the chamber. This removes any vacuum that may be present.
16. Remove the four 4 mm hex bolts securing the door in the closed position.
17. Remove the two 6 mm hex bolts securing the counterweight.

*Note: The screws are behind neoprene and fit through the chamber flange into the door.*

18. Manually open the door by pushing down on the top of the door. The door should open with ease. Remove the boxes from inside the system.

*Note: The boxes shipped with the system contain vacuum system parts and other system accessories. Be sure to unpack the boxes completely before discarding.*

19. If you are going to move the unit to a different site, replace the side and lower back panels.
20. Once the unit is in position in the installation site, remove all exterior panels and temporarily store them in a safe location.

# Installing the Seismic Restraints

This procedure is approved by the State of California Building Code as a valid seismic restraint procedure and is required for units installed in California. Customers in other states or countries, or ships at sea, may need to have seismic restraints installed.

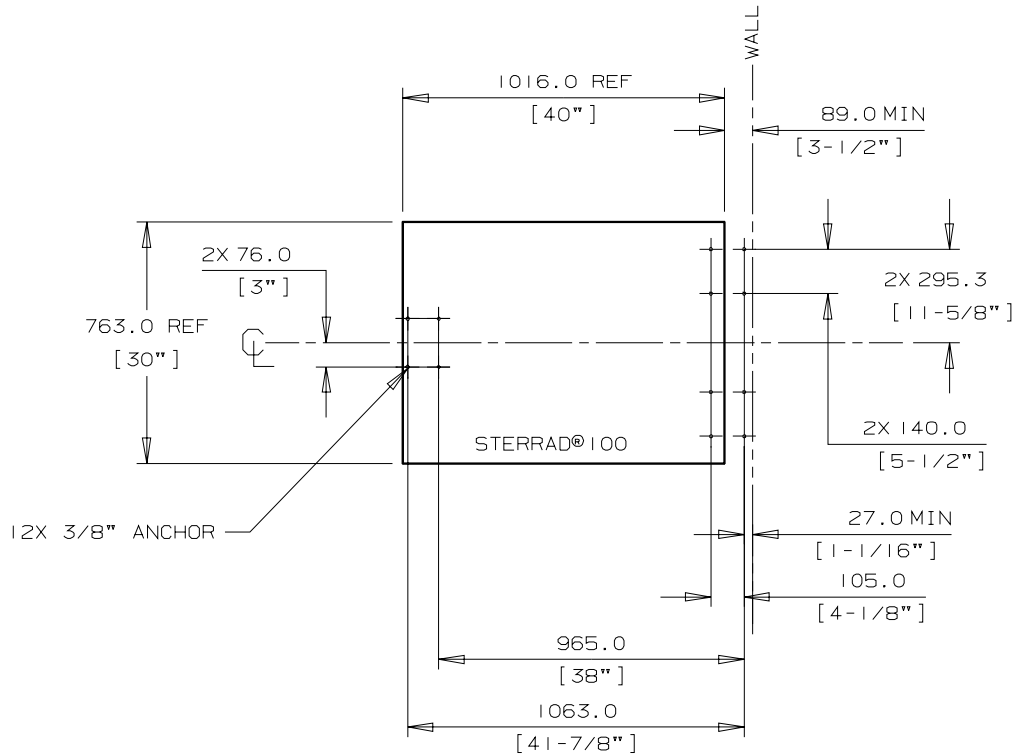
The Seismic Restraint installation kit contains:

- two brackets
- attachment hardware
- drilling template

The kit should be ordered from Customer Service and the installation coordinated by ASP Technical Services.

## Pre-Installation Procedure-To Be Done by the Customer

The customer must identify the location for the sterilizer and perform steps 1-4 below prior to any other installation procedures.



OPTIONAL MOUNTING PATTERN

(CONTACT ASP FOR ADDITIONAL INFORMATION ON SEISMIC RESTRAINT WITHIN THE STATE OF CALIFORNIA)

Seismic Restraint Mounting Configuration (Facility to mount anchors in floor)

Figure 3. Optional Mounting Plan

*Note: There is a drilling template included in the kit.  
It has the proper dimensions and drilling  
positions.*

1. Position the rear bracket on the floor about 2 inches away from the wall (1-1/16 inches minimum) and mark the location of the holes for drilling. If there is an outlet in the wall at the desired installation location, add at least 3 inches to the distance.

2. Using the dimensions in the preceding figure, and in the kit diagrams, measure carefully and position the front bracket on the floor (about 33 inches from the rear bracket). Mark the location of the holes for drilling.
3. Drill 12 each, 3/8 inch holes in the floor. (Use the manufacturer's recommendation for the anchor bolts if the size is different than 3/8 inch.)

*Note: Use only approved anchor bolts shown in the table. (S=standard steel, SS=stainless steel).*

Concrete Type	Min. fc (psi)	3/8 " Anchor Type	ICBO Report #	Min Embedment (inches)	Test Loads
Hardrock	2000	Hilti Kwikbolt II (S) (SS)	4627	1-5/8	Direct Pull Tension -1100 lbs Torque 25 ft/lbs
		Rawl Stud (S) (SS)	4514	1-5/8	
		ITW/Ramset Trubolt (S) (SS)	1372	1-1/2	
		Wej-It Anchor Bolt (S)	1821	1-1/2	
Lightweight	3000	Hilti Kwik Bolt II (S) (SS)	4627	1-5/8	Direct Pull Tension -700 lbs Torque 10 ft/lbs
		ITW/Ramset Trubolt (S) (SS)	1372	1-11/16	
		ITW/Ramset Dynabolt (S) (SS)	1372	1-1/2	

4. Using a hammer, drive the anchor bolts into the holes drilled in the floor. Please allow enough room to mount the bracket, washer, and nut.

## Installing the Brackets

1. Fasten the rear bracket onto the anchor bolts using the 3/8" wide flat washers and the nuts supplied with the anchor bolts. See the preceding figure.
2. Remove the rubber tipped spindles on the locating pins. Then loosen the 2 locating pins on the rear bracket. There are 4 mounting bolts on the bracket, loosen them with a 1/2" box wrench.
3. Loosely fasten the wheel guides onto the unit.
4. If the drilling template was used, it should be completely removed, including the tape holding it, by this point.
5. Move the sterilizer so that the subframe channels align with locating pins on the rear seismic bracket.
6. Tighten the 4 mounting bolts on each locating pin. Tighten the wheel guides.
7. Pull the sterilizer away from the rear locating pins. Ensure that unit pulls out easily. The level of the floor may affect the locating pins tightness into the channel.
8. Attach the front bracket to the anchor bolts using the 3/8" wide flat washers and the nuts supplied with anchor bolts.
9. Adjust the rubber-tipped bumpers to stop the unit when the anchor pins line up with the front bracket.
10. Raise or lower the anchor pin until it is at a height to fit in the front bracket key slot.
11. With the rear panel in place, adjust the rubber-tipped spindles until the sterilizer is stopped with the anchor pin in line with the front bracket. Tighten the spindles.
12. Raise the anchor pin until it barely clears the bottom of the key slot.
13. Using an Allen wrench, lower the front locking mechanism to the point where the STERRAD 100S Sterilizer is locked in place. (An M4 Allen wrench should work.)
14. Tighten the M10 jam nut.
15. Replace the panels.

# Vacuum Subsystem Assembly

Prior to assembling the unit make sure the following are completed or verified:

- All vacuum fittings must be clean and free of foreign material.
- Lightly coat all O-rings and seals with a thin film of high vacuum grease before installation.
- KF clamps are supplied with wing nuts and should never be tightened more than finger tight. Do not use tools to tighten.
- Change the oil in the vacuum pump.

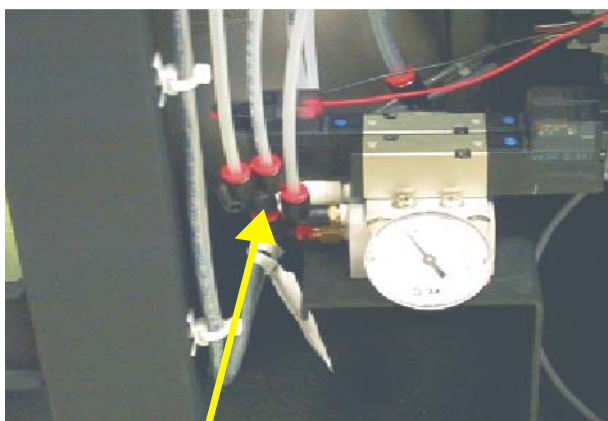
**CAUTION: REMOVE the exhaust port blanking flange prior to operating the pump. Operating the vacuum pump with the exhaust port blanking flange installed can cause permanent internal damage to the pump.**

1. Locate the installation parts box attached to the frame member. (This box used to contain the throttle valve assembly.) This box now contains the on/off vacuum control valve, manifold assembly, clamps, centering rings, bellows, and atmospheric switch. (See Figure 4.)



Figure 4. Vacuum Control Assembly Parts

2. Attach the atmospheric switch to the manifold assembly containing the vent valve and HEPA filter.
3. Attach the manifold assembly to the bottom of the chamber.
4. Attach the bellows to bottom of the manifold assembly.
5. Attach the On/Off valve between the bellows and the vacuum pump.
6. Connect the harness from the On/Off valve to the PWA mounted on the control enclosure.
7. Connect the tubing from the pneumatic solenoid T-fitting to the On/Off valve. (See Figure 5.)



## T-Connection

**Figure 5. Tubing Connection from Solenoid to On/Off Valve.**

8. Remove the drain plugs and install the oil return fitting. Use the existing drain plug washer with the new fitting.
9. Attach the oil return line that connects the oil return solenoid and the exhaust filter.
10. Verify that the vacuum pump is filled with oil to the white indicator line.
11. Switch the gas ballast valve to OPEN.
12. Connect the throttle valve harness, vent valve, oil return solenoid and vacuum switch electrical connections.



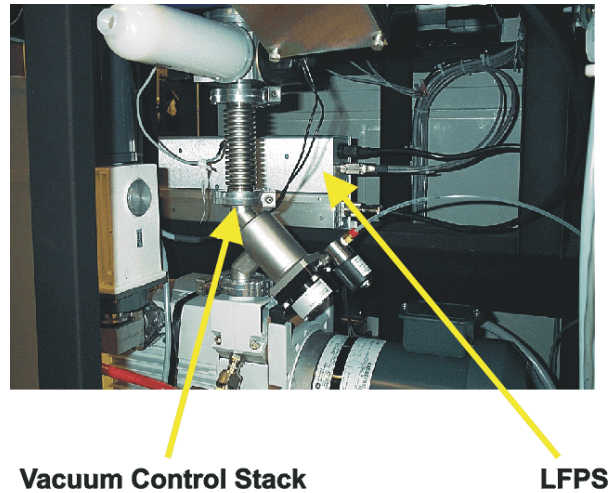


Figure 6. Correctly Assembled Vacuum Stack.

## System Configurations

Systems are shipped with the final, language-specific configurations yet to be done. The final configuration information and parts are in a kit that is shipped with the system. The receiving organization finishes the system and returns the completion notification to ASP. The instructions for this configuration are as follows:

### Attach Machine Label

1. Remove side panels and rear panels.
2. Locate the label that is in the correct language for the country receiving the unit.
3. Remove the rear cover of the AC enclosure.
4. Clean the lower left rear corner of the AC cover with 3M natural cleaner (or equivalent) and attach the chosen label (item 2) to the rear cover (item 6) as shown, so that it is readable. Press down firmly to remove any trapped air.

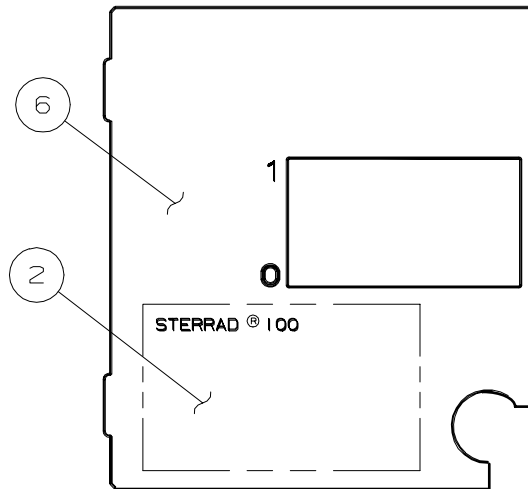


Figure 7. International Label Position.

5. Attach the labeled cover to the rear of the AC Enclosure and secure by hooking the tabs into the slots and securing the PEM studs inside the enclosure with 2 each, M4 Flat washers and M4 Hex Lock nuts.

## Thermal Overload Relay

**WARNING! POWER MUST BE OFF AND THE POWER CORD DISCONNECTED FROM THE SYSTEM.**

1. Attach the thermal overload relay to the AC interface enclosure.
2. Switch the mounting pins so that the two movable pins are set to outboard (widest) location.
3. Lift the clear plastic cover and set the overload to 3.6 amps, for the low voltage units (200 VAC, 208 VAC) and 1.8 amps for high voltage units (308 VAC, 398 VAC, 415 VAC).
4. Replace the clear plastic cover.

*Note: Terminations ending in a clamping device should have only the stripped wire inside the clamp. The insulation should not be inside the clamp.*

5. Connect orange wire #80 to CR3-NC 95.

6. Connect orange wire #90 to CR3-NC 96.
7. Connect black wire #29 to CR3-T1.
8. Connect blue wire #30 to CR3-T2.
9. Connect red wire #31 to CR3-T3.
10. Install CR3 to CR2 by hooking CR3 into the cover of CR2 and inserting pins into CR2-T1, T2, and T3. Secure the terminal screws.
11. Attach the configuration PWA to the standoffs in the control enclosure and plug the connectors into the PWA.

## Power Plug

1. If not already installed, install a plug to the power cord for the correct voltage for your country. Connect as shown in the table below.

Wire Number	Color and Number	P80-Connect
1	Black 1	P80-X
2	Black 2	P80-Y
3	Black 3	P80-Z
4	Black 4	P80-W
5	Green/Yellow	P80-Ground

## Control Panel Bezel

1. Remove the plastic cover from the **INSIDE** of the clear plastic window. **DO NOT** remove the outer protective plastic overlay.
2. Press the control bezel into place on the front of the control panel until pins lock in the detents and the panel is flush with the front surface of the bezel.

# Software Installation

**CAUTION: You MUST WORK AT A STATIC PROTECTED WORKSTATION, BE GROUNDED AT ALL TIMES, AND CONFORM TO ELECTROSTATIC CONTROL PROCEDURES. A WRIST STRAP CONNECTED TO THE FRAME OF THE MACHINE IS NOT GROUNDED UNLESS THE MACHINE IS PLUGGED INTO AN EARTH GROUND.**

1. Verify that the main circuit breakers are OFF.
2. Plug the machine to a grounded receptacle.
3. If you are setting up the system to operate in a language other than English, remove the microprocessor PWA, remove the EPROM and replace it with the appropriate language EPROM. Note the check sum listed on the EPROM. Place the removed EPROM in a static safe area.

**CAUTION! Pay particular attention to the orientation of the EPROM during insertion into its IC socket. Additionally, exercise care to ensure that the EPROM pins are not bent, broken, or otherwise damaged during insertion.**

4. Remove the "Remove Before Use" battery insulator between the battery and contact of the microprocessor PWA and affix it to the DHR.
5. Carefully attach the microprocessor PWA inside the to control enclosure.
6. Ensure that all PWAs are firmly seated in the card cage. Make sure the safety switch cannot be activated.

# System Reset

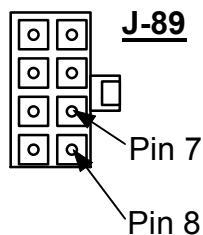
1. Turn the circuit breakers ON.
2. Press and hold **CANCEL** and at the same time close the control enclosure cover to activate the safety switch and turn the unit on.
3. Continue to hold **CANCEL** until the machine beeps.
4. Fully engage the enclosure cover screws and lock finger tight.

# Set System Parameters

## Verify Voltages

1. Measure AC voltages for chamber and door heaters, control enclosure, LFPS, vaporizer, and compressor. Refer to chart for version main line voltage and nominal voltages expected  $\pm 10\%$  for each circuit.

Main Line Voltage Version						
		200 VAC	208 VAC	380 VAC	398 VAC	415 VAC
Feature	Measure Input Voltage At		208V-60	380V-50	380V-50	380V-50
LFPS	CB7 A-B	200	220	220	220	220
Chamber Heaters	CB6 A-B	200	208	220	220	220
Door Heaters	CB4 A-B	200	208	220	220	220
Control Enclosure	CB3 A-B	120	120	120	120	120
Vaporizer	J-89 pin 7, 8	25	25	25	25	25
Compressor	Utility J-83B	120	120	120	110	120

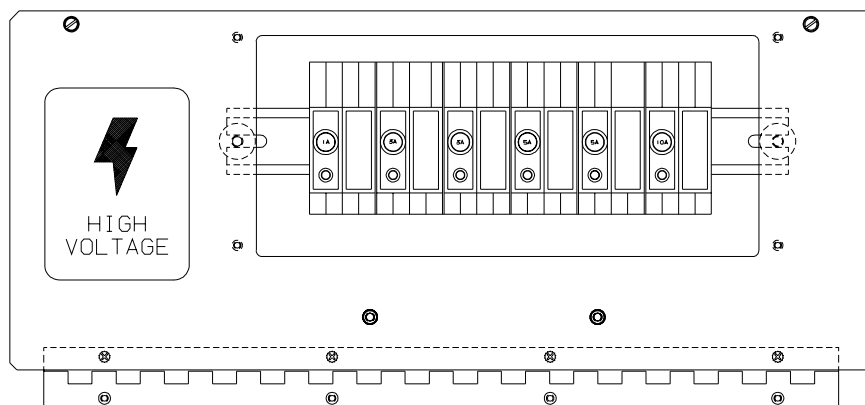


## Install Printer Ribbon and Paper

1. Install the printer ribbon.
2. Install a roll of paper in the printer. Place the rest of the paper in the accessory box for shipment to the customer.

## Power Connection

1. Verify that the main circuit breaker located on the AC interface assembly is in the OFF position.
2. Plug the vacuum pump AC power connector into the designated receptacle on the AC enclosure.
3. Check all circuit breakers located on the AC enclosure. The circuit breakers are on the side of the unit and accessible with the panels in place. Verify that all circuit breakers are ON. Movement during shipping may cause the circuit breakers to trip.



**Figure 8. Circuit Breakers.**

4. Check that all of the connectors throughout the entire machine are in place and correctly mated. Some of the connectors may have worked loose in shipment.
5. Remove both control enclosure panels and ensure that all cables attached to the connector distribution PCBs are secure. Verify that the 3 PCBs are fully inserted into their sockets.
6. Plug the system into the outlet.

## Phase Rotation

1. Start a cycle with no cassette and verify that the vacuum pump rotation is correct. Air blows out of the air mist filter housing when correct.

*Note: If air is entering into the oil mist filter housing, immediately remove power from the system. Disconnect the power cord from the wall and correct the phasing of the power at the wall receptacle.*

2. If the phase is incorrect, the system generates a **VACUUM SYSTEM INTERRUPTED** message in 30 seconds and stops the vacuum pump.

## Preparing The System For Use

1. Open the accessories boxes shipped with the system. Remove all materials.
2. Install all the accessories in their proper locations. Make sure to wipe off any fingerprints or packaging material that may be present.
3. Set the cycle type according to the customer's needs.

## Initialization

The system must be initialized prior to use. The Master Reset procedures must be followed in the sequence given to accurately reset all system variables.

The Master Resets are a series of steps used to initialize the system. They are also used for troubleshooting various error messages. The steps are: system reset, system variables reset, cassette collector box reset, date and time reset, and PM log reset.

### **System Reset**

**WARNING! Do not perform the master reset when a cycle is in progress. Perform only when the system is in the idle state.**

1. Remove any cassettes that may be in the injector pump. Discard according to accepted procedures.
2. Turn the main circuit breaker ON and perform a system reset by pressing **CANCEL** for ten seconds at the same time power is applied. The system sounds a beep tone when this process is completed and displays the date, STERRAD® 100S Sterilizer software part number, and check sum.

### **Enter the Edit Mode**

1. To enter the EDIT mode, press **CANCEL**.
2. Press and hold **CANCEL** and simultaneously press **START**. This opens the Date-Time menu.

**DATE = DAT MM/DD/YY**  
**OPEN(chng)- CLOSE(accept)**

**TOTAL MACHINE CYCLES      0**

3. Press **CANCEL** to move sequentially through the available menus.

### **System Variables Reset**

1. Enter the edit mode. Simultaneously press and hold **START** and **OPEN DOOR** for 5 seconds. After 5 seconds, the system displays the total machine cycles.
2. Write down the number of **TOTAL MACHINE CYCLES** displayed on the LCD, then reset the total machine cycles to 0.
3. Return to the active display by simultaneously pressing **START** and **OPEN DOOR** (the display switches to the edit date/time display). Then simultaneously press **START** and **CANCEL** to return to the active display.



4. Reenter the edit mode, as shown previously and change the total machine cycles to the number you wrote down in step 4.
5. Press **CANCEL** and the system displays the serial number as follows:

**SERIAL NUMBER XXXXX**  
**OPEN (change) - CLOSE (accept)**

*Note: The serial number is located on the frame behind the storage drawer.*

6. A flashing cursor is displayed on the serial number field. To enter the serial number, press and hold **OPEN DOOR** until the desired number is selected. Alternate between the field numbers by pressing the **CLOSE DOOR** switch.
7. Simultaneously press **START** and **OPEN DOOR** (the display switches to the edit date/time display). Then simultaneously press **START** and **CANCEL** to return to the active display.

#### **Cassette Collector Box Reset**

1. Remove the cassette collector box from the box base assembly.
2. Reinstall the collector box after the system has signaled reset by a single beep tone (approximately 10 seconds).

#### **Date and Time Reset**

1. Enter the edit mode by pressing **START** and **CANCEL** at the same time. The LCD display shows the following:

**DATE = DAY, MM/DD/YY**  
**OPEN(change) - CLOSE (accept)**

2. DAY is a three letter abbreviation for the day of the week e.g., WED; MM is the month, e.g., 03; DD is the numerical day, e.g., 25; and YY is the year, e.g., 95. A flashing cursor is displayed on the DAY field.
3. To change the displayed day, press **OPEN DOOR** until the desired day is selected. When the correct day is displayed, press **CLOSE DOOR** to move to the month MM field.

4. Press **OPEN DOOR** to change the MM, DD, and YY each in turn until the desired setting is displayed. Press **CLOSE DOOR** each time to move the cursor to the next field. After the YY is updated, the following message is displayed on the LCD:

**TIME=HH:MM:SS AM**  
**OPEN(change) - CLOSE (accept)**

HH is the hour of the day, e.g., 09; MM is the minutes, e.g., 12; SS is the seconds, e.g., 43; AM represents after midnight and PM represents after noontime.

5. Press **OPEN DOOR** to change the HH, MM, and SS each in turn until the desired setting is displayed. Press **CLOSE DOOR** each time to move the cursor to the next field. After the AM/PM is updated, the current date is displayed.
6. After the desired date and time settings have been obtained, simultaneously press **START** and **CANCEL** to exit the month/time program and continue to the PM Log Rest.

### **PM Log Reset**

1. Press **OPEN DOOR** and **START** to enter the edit mode. The system displays the total machine cycles. Press **CANCEL** to display the PM warning. Press **CANCEL** again to display PM 1500 L1. The display looks like the following example:

**P.M. Y: NEXT PM 1500 L1**  
**OPEN (reset) - CANCEL (next)**

*Note: The cursor flashes on the N/Y field. The NEXT PM field displays the total remaining cycles before the system stops running cycles.*

2. Press **OPEN DOOR** to change the N default to Y (indicating maintenance has been completed). Verify that the NEXT PM field resets to the total allowable cycles (1500) between maintenance intervals.
3. Press **CANCEL** (display moves to date), then press **START** and **CANCEL** at the same time. The system display returns to the ready state and prints the Maintenance Log.

## **Replace the Panels**

1. Replace the system panels.
2. Perform a complete system certification.

## **Perform BI Validation**

1. Perform a complete BI validation and keep the records.

## Final Procedures

The system must pass the product certification and biological acceptance procedure after installation.

1. Fill out the required forms and send or fax them to the appropriate location.
2. If the unit is being shipped to another location, return it to the shipping crate and make sure it is correctly packed and secured.

## Certification Statement Instructions

Complete the certification statement and fax it back after the configuration has been done. The system serial number, configuration kit number, LC number, and country of origin **MUST** be included on the form for proper certification.

1. Enter the complete system serial number.
2. Enter the configuration kit number.
3. Fill in your name, ASP service location, country, and date and phone/fax numbers.
4. Enter the LC number from the label.
5. Fax the entire certification back to the number provided.